IN THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA SAN JOSE DIVISION TEVA PHARMACEUTICALS USA, INC., Plaintiff, v. CORCEPT THERAPEUTICS, INC., AND OPTIME CARE INC., Defendants.

Case No. 5:24-cv-03567-NW

STIPULATED PROTECTIVE ORDER

1. PURPOSES AND LIMITATIONS

Disclosure and discovery activity in this action are likely to involve production of confidential, proprietary, or private information for which special protection from public disclosure and from use for any the Court enters the purpose other than prosecuting this litigation may be warranted. Accordingly, the Parties hereby stipulate to following and petition the Court to enter the following Stipulated Protective Order ("Order"). The Parties acknowledge that this Order does not confer blanket protections on all disclosures or responses to discovery and that the protection it affords from public disclosure and use extends only to the limited information or items that are entitled to confidential treatment under the applicable legal principles. The Parties further acknowledge, as set forth in Section 14.4, below, that this Order does not entitle them to file confidential information under seal; Civil Local Rule 79-5 sets forth the procedures that must be followed and the standards that will be applied when a Party seeks permission from the court to file material under seal.

2. **DEFINITIONS**

- 2.1 <u>Challenging Party</u>: a Party or Non-Party that challenges the designation of information or items under this Order.
- 2.2 "CONFIDENTIAL" Information or Items: information (regardless of how it is generated, stored or maintained) or tangible things the "Designating Party" considers in good faith: (i) contains trade secrets, competitively sensitive technical, marketing, financial, sales, commercial, or other confidential business information, or (ii) contains private or confidential personal information, including, but not limited to Protected Health Information, or (iii) contains information received in confidence from third parties, or (iv) which the Designating Party otherwise believes in good faith to be entitled to protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure. Confidential Information shall include, but not be limited to, New Drug Applications, including all supplements, updates, amendments and revisions thereto. Confidential information also includes: (i) information copied or extracted, summarized, or compiled from Confidential Information; and (ii) testimony, conversations, communications, or presentations by Parties or their Counsel that might reveal Confidential Information.
- 2.3 <u>Counsel (without qualifier)</u>: Outside Counsel of Record and House Counsel (as well as their support staff).

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- 2.4 Covered Entities: shall have the same scope and definition as set forth in 45 C.F.R. § 160.103.
- 2.5 De-Identified Information: shall have the same scope and definition as set forth in 45 C.F.R. § 164.514(a).
- 2.6 Designating Party: a Party or Non-Party that designates information or items that it produces in disclosures or in responses to discovery as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL -OUTSIDE ATTORNEYS' EYES ONLY."
- 2.7 Disclosure or Discovery Material: all items or information, regardless of the medium or manner in which it is generated, stored, or maintained (including, among other things, testimony, transcripts, and tangible things), that are produced or generated in disclosures or responses to discovery in this matter.
- 2.8 Expert: a person with specialized knowledge or experience in a matter pertinent to the litigation who has been retained by a Party or its counsel to serve as an expert witness or as a consultant in this action. For the avoidance of doubt, this definition also includes the Expert's support staff.
- 2.9 "HIGHLY CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY" ("Highly Confidential") Information or Items: extremely sensitive "Confidential Information or Items," disclosure of which to another Party or Non-Party would create a substantial risk of serious harm that could not be avoided by less restrictive means. Subject to such qualifier, such information may fall into one or more of the following categories: (i) highly sensitive trade secrets, intellectual property, or proprietary technical information, including, without limitation, research information, design and technical documents and internal product specifications; (ii) highly sensitive business, financial or marketing information, including, without limitation, licenses, forecasts, customer lists, pricing data, cost data, customer orders, customer quotations and marketing plans; (iii) pending or abandoned patent, trademark and copyright applications, foreign or domestic, unless published or otherwise publicly available; (iv) Protected Health Information; or (v) other proprietary information that the Designating Party believes is entitled to extraordinary protection or is of such nature and character that the unauthorized disclosure of such information is likely to harm the competitive or economic position of the Designating Party or provide improper advantage to others. Highly Confidential information also includes: (i) information copied or extracted, summarized, or compiled from Highly Confidential Information; and (ii) testimony, conversations, communications, or presentations by Parties or their Counsel that might reveal Highly Confidential Information.

- 2.10 <u>House Counsel</u>: attorneys or individuals responsible for management of litigation, who are employees of a party to this action. House Counsel does not include Outside Counsel of Record or any other outside counsel.
 - 2.11 <u>Individual</u>: shall have the same scope and definition as set forth in 45 C.F.R. § 160.103.
- 2.12 <u>Non-Party</u>: any natural person, partnership, corporation, association, or other legal entity not named as a Party to this action.
- 2.13 Outside Counsel of Record: attorneys who are not employees of a party to this action but are retained to represent or advise a party to this action and have appeared in this action on behalf of that party or are affiliated with a law firm which has appeared on behalf of that party.
- 2.14 <u>Party</u>: any party to this action, including all of its officers, directors, employees, consultants, retained experts, and Outside Counsel of Record (and their support staffs).
- 2.15 <u>Producing Party</u>: a Party or Non-Party that produces Disclosure or Discovery Material in this action.
- 2.16 <u>Professional Vendors</u>: persons or entities that provide litigation support services (*e.g.*, photocopying, videotaping, translating, preparing exhibits or demonstrations, and organizing, storing, or retrieving data in any form or medium) and their employees and subcontractors.
- 2.17 <u>Protected Health Information (PHI)</u>: shall have the same scope and definition as set forth in 45 C.F.R. § 160.103, and includes, but is not limited to, health information, including demographic information, relating to either: (a) the past, present, or future physical or mental condition of an individual, (b) the provision of health care to an individual, or (c) the payment for the provision of health care to an individual, which identifies the individual or which reasonably could be expected to identify the individual.
- 2.18 <u>Protected Material</u>: any Disclosure or Discovery Material that is designated as "CONFIDENTIAL," or as "HIGHLY CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY."
- 2.19 <u>Receiving Party</u>: a Party that receives Disclosure or Discovery Material from a Producing Party.

3. SCOPE

The protections conferred by this Order cover not only Protected Material (as defined above), but also (1) any information copied or extracted from Protected Material; (2) all copies, excerpts, summaries, or

compilations of Protected Material; and (3) any testimony, conversations, or presentations by Parties or their Counsel that might reveal Protected Material. However, the protections conferred by this Order do not cover the following information: (a) any information that is in the public domain at the time of disclosure to a Receiving Party or becomes part of the public domain after its disclosure to a Receiving Party as a result of publication not involving a violation of this Order, including becoming part of the public record through trial or otherwise; and (b) any information known to the Receiving Party prior to the disclosure or obtained by the Receiving Party after the disclosure from a source who obtained the information lawfully and under no obligation of confidentiality to the Designating Party; and (c) any PHI that was received by means other than through this Order (for example, through consent of the individual or through a public records request). Except as provided herein, any use of Protected Material during any court hearing or at trial shall be governed by a separate agreement or order. The Parties shall give any Producing Party adequate notice if they reasonably expect a court hearing to include Protected Materials so that the Producing Party can take any steps necessary

4. <u>DURATION</u>

Even after final disposition of this litigation, the confidentiality obligations imposed by this Order shall remain in effect until a Designating Party agrees otherwise in writing or a court order otherwise directs. Final disposition shall be deemed to be the later of (1) dismissal of all claims and defenses in this action, with or without prejudice; and (2) final judgment herein after the completion and exhaustion of all appeals, rehearings, remands, trials, or reviews of this action, including the time limits for filing any motions or applications for extension of time pursuant to applicable law.

for the Producing Party to retain the Confidentiality of any such Protected Materials.

5. DESIGNATING PROTECTED MATERIAL

5.1 <u>Exercise of Restraint and Care in Designating Material for Protection</u>. Each Party or Non-Party that designates information or items for protection under this Order must take care to limit any such designation to specific material that qualifies under the appropriate standards.

Mass, indiscriminate, or routinized designations are prohibited. Designations that are shown to be clearly unjustified or that have been made for an improper purpose (*e.g.*, to unnecessarily encumber or retard the case development process or to impose unnecessary expenses and burdens on other parties) expose the Designating Party to sanctions.

If it comes to a Designating Party's attention that information or items that it designated for protection do not qualify for protection at all or do not qualify for the level of protection initially asserted, that Designating Party must promptly notify all other parties that it is withdrawing the mistaken designation.

5.2 <u>Manner and Timing of Designations</u>. Except as otherwise provided in this Order (*see*, *e.g.*, Section 5.2(a) below), or as otherwise stipulated or ordered, Disclosure or Discovery Material that qualifies for protection under this Order must be clearly so designated before the material is disclosed or produced.

Designation in conformity with this Order requires:

- (a) <u>for information in documentary form</u> (*e.g.*, paper or electronic documents, but excluding transcripts of depositions or other pretrial or trial proceedings), that the Producing Party affix the legend "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY" to each page that contains protected material.
- (b) <u>for testimony given in deposition or in other pretrial or trial proceedings</u>, a Designating Party shall have up to 30 days after the date when a complete and final copy of the deposition transcript has been made available to identify the specific portions of the testimony as to which protection is sought and to specify the level of protection being asserted. Only those portions of the testimony that are appropriately designated for protection within the 30 day period shall be covered by the provisions of this Order. Alternatively, when it is impractical to identify separately each portion of testimony that is entitled to protection and it appears that substantial portions of the testimony may qualify for protection, a Designating Party may specify that the entire transcript shall be treated as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY."

The Parties shall give one another and any affected Non-Party notice if they reasonably expect a court hearing to include Protected Material so that the other parties can ensure that only authorized individuals who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A) are present at those proceedings. The use of a document as an exhibit at a deposition shall not in any way affect its designation as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY."

Transcripts containing Protected Material shall have an obvious legend on the title page that the transcript contains Protected Material, and the title page shall be followed by a list of all pages (including line numbers as appropriate) that have been designated as Protected Material and the level of protection being

asserted by the Designating Party. The Designating Party shall inform the court reporter of these requirements. Any transcript that is prepared before the expiration of a 30-day period for designation shall be treated during that period as if it had been designated "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY" in its entirety, unless otherwise agreed. After the expiration of that period, the transcript shall be treated only as actually designated.

- (c) <u>for information produced in some form other than documentary and for any other tangible items</u>, that the Producing Party affix in a prominent place on the exterior of the container or containers in which the information or item is stored the legend "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY." If only a portion or portions of the information or item warrant protection, the Producing Party, to the extent practicable, shall identify the protected portion(s) and specify the level of protection being asserted.
- 5.3 <u>Inadvertent Failures to Designate</u>. If timely corrected, an inadvertent failure to designate qualified information or items does not, standing alone, waive the Designating Party's right to secure protection under this Order for such material. Upon timely correction of a designation, the Receiving Party must make reasonable efforts to assure that the material is treated in accordance with the provisions of this Order.

6. CHALLENGING CONFIDENTIALITY DESIGNATIONS

- 6.1 <u>Timing of Challenges</u>. Any Party may challenge a designation of confidentiality at any time. Unless a prompt challenge to a Designating Party's confidentiality designation is necessary to avoid foreseeable, substantial unfairness, unnecessary economic burdens, or a significant disruption or delay of the litigation, a Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed.
- 6.2 <u>Meet and Confer.</u> The Challenging Party shall initiate the dispute resolution process by providing written notice of each designation it is challenging and describing with particularity the basis for each challenge. To avoid ambiguity as to whether a challenge has been made, the written notice must recite that the challenge to confidentiality is being made in accordance with this specific paragraph of the Protective Order. The Parties shall attempt to resolve each challenge in good faith and must begin the process by conferring directly (in voice to voice dialogue; other forms of communication are not sufficient) within 14 days of the date of service of notice. In conferring, the Challenging Party must explain the basis for its belief

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that the confidentiality designation was not proper and must give the Designating Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain the basis for the chosen designation. A Challenging Party may proceed to the next stage of the challenge process only if it has engaged in this meet and confer process first or establishes that the Designating Party is unwilling to participate in the meet and confer process in a timely manner.

6.3 <u>Judicial Intervention</u>. If the Challenging Party and the Designating Party cannot resolve a challenge without court intervention, they shall comply with the discovery dispute procedures set out in Judge DeMarchi's Standing Order for Civil Cases. Failure by the Parties to seek court intervention within the period set out in the Standing Order for Civil Cases shall not automatically waive the confidentiality designation for each challenged designation. In addition, the Challenging Party may seek relief with respect to a confidentiality designation at any time if there is good cause for doing so, including a challenge to the designation of a deposition transcript or any portions thereof. In any discovery letter brief brought pursuant to this provision, the parties shall attest that they have complied with the meet and confer requirements imposed in the preceding paragraph.

The burden of persuasion in any such challenge proceeding shall be on the Designating Party. Frivolous challenges and those made for an improper purpose (e.g., to harass or impose unnecessary expenses and burdens on other parties) may expose the Challenging Party to sanctions. All parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation until the court rules on the challenge.

7. ACCESS TO AND USE OF PROTECTED MATERIAL

Basic Principles. A Receiving Party may use Protected Material that is disclosed or produced by another Party or by a Non-Party in connection with this case only for prosecuting, defending, or attempting to settle this litigation. Such Protected Material may be disclosed only to the categories of persons and under the conditions described in this Order. Upon the final disposition of this action, as defined in Section 4 (DURATION), a Receiving Party must comply with the provisions of Section 15 below (FINAL DISPOSITION).

Protected Material must be stored and maintained by a Receiving Party at a location and in a secure manner that ensures that access is limited to the persons authorized under this Order.

- 7.2 <u>Disclosure of "CONFIDENTIAL" Information or Items</u>. Unless otherwise ordered by the court or permitted in writing by the Designating Party, a Receiving Party may disclose any information or item designated "CONFIDENTIAL" only to:
- (a) the Receiving Party's Outside Counsel of Record in this action, as well as employees of said Outside Counsel of Record to whom it is reasonably necessary to disclose the information for this litigation;
- (b) the officers, directors, and employees (including House Counsel) of the Receiving Party to whom disclosure is reasonably necessary for this litigation and who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A);
- (c) Outside Experts and consultants (e.g., non-testifying experts and trial consultants) and their staff retained to assist the parties in the conduct of these actions who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A);
 - (d) the court and its personnel;
- (e) persons or entities that provide litigation support services retained by a Party or a Party's Outside Counsel of Record, including but not limited to court reporters and their staff, professional jury or trial consultants, and Professional Vendors as well as their employees and subcontractors, to whom disclosure is reasonably necessary for this litigation and who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A);
- (f) any mediators engaged by the Parties, and their support staff, who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A);
- (g) during their depositions or trial testimony, witnesses in the action to whom disclosure is reasonably necessary and who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A), unless otherwise agreed by the Designating Party or ordered by the Court. Pages of transcribed deposition testimony or exhibits to depositions that reveal Protected Material must be separately bound and for electronic versions, segregated, by the court reporter and may not be disclosed to anyone except as permitted under this Order;
- (h) as determined by Counsel or the Receiving Party on a good-faith basis, the author, addressee, recipient, custodian, or source of a document containing the information or other person who otherwise possessed, knew, or had access to the information; and

- (i) any current employee of a Designating Party may be examined at trial or upon deposition concerning any information designated "CONFIDENTIAL" by such Party.
- 7.3 <u>Disclosure of "HIGHLY CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY"</u>
 <u>Information or Items</u>. Unless otherwise ordered by the Court or permitted in writing by the Designating Party, a Receiving Party may disclose any information or item designated "HIGHLY CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY" only to:
- (a) the Receiving Party's Outside Counsel of Record in this action, as well as employees of said Outside Counsel of Record to whom it is reasonably necessary to disclose the information for this litigation;
- (b) Outside Experts and consultants (e.g., non-testifying experts and trial consultants) and their staff retained to assist the parties in the conduct of these actions who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A);
 - (c) the Court and its personnel;
- (d) persons or entities that provide litigation support services retained by a Party or a Party's Outside Counsel of Record including but not limited to court reporters and their staff, professional jury or trial consultants, and Professional Vendors as well as their employees and subcontractors, to whom disclosure is reasonably necessary for this litigation, and who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A);
- (e) any mediators engaged by the Parties, and their support staff, who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A);
- (f) during their depositions or trial testimony, the author, addressee, recipient, custodian, or source of a document containing the information or other person who otherwise possessed, knew, or had access to the information. Pages of transcribed deposition testimony or exhibits to depositions that reveal Protected Material must be separately bound, and for electronic versions, segregated, by the court reporter and may not be disclosed to anyone except as permitted under this Order;
- (g) as evidenced by the face of or metadata produced with the Protected Material, the author, addressee, or recipient of a document containing the information or a custodian or other person who otherwise possessed, knew, or had access to the information; and
 - (h) any current employee of a Designating Party may be examined at trial or upon deposition

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- 7.4 Procedures for Approving or Objecting to Disclosure of "HIGHLY CONFIDENTIAL -OUTSIDE ATTORNEYS' EYES ONLY" Information or Items
- (a) Unless otherwise ordered by the court or agreed to in writing by the Designating Party, a Party that seeks to disclose to an Expert in the fields of marketing, development, and/or approval of pharmaceutical products any information or item that has been designated "HIGHLY CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY" pursuant to paragraphs 7.2(c) or 7.3(c) first must give notice to the Designating Party that (1) identifies the general categories of "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS" EYES ONLY" information that the Receiving Party seeks permission to disclose to the Expert, (2) sets forth the full name of the Expert and the city and state of his or her primary residence, (3) attaches a copy of the Expert's current curriculum vitae including at least 5 years of work history, (4) identifies the Expert's current employer(s), (5) identifies each person or entity from whom the Expert has received compensation or funding for work in his or her areas of expertise or to whom the expert has provided professional services, including in connection with a litigation, at any time during the preceding five years, and (6) identifies (by name and number of the case, filing date, and location of court) any litigation in connection with which the Expert has offered expert testimony, including through a declaration, report, or testimony at a deposition or trial, during the preceding five years. A Party that makes a request and provides the information specified in the preceding respective paragraphs may disclose the subject Protected Material to the identified Expert unless, within 14 days of delivering the request, the Party receives a written objection from the Designating Party. Any such objection must set forth in detail the grounds on which it is based.
- (b) A Party that receives a timely written objection must meet and confer with the Designating Party (through direct voice to voice dialogue) to try to resolve the matter by agreement within seven days of the written objection. If no agreement is reached, the parties shall comply with the discovery dispute procedures set out in Judge DeMarchi's Standing Order for Civil Cases.
- In any such proceeding, the Party opposing disclosure to the Expert shall bear the burden of (c) proving that the risk of harm that the disclosure would entail (under the safeguards proposed) outweighs the Receiving Party's need to disclose the Protected Material to its Expert.

7.5 Requests to Disclose Protected Material. A Party seeking to disclose Protected Material to a person not authorized to access such Protected Material pursuant to Sections 7.2 and 7.3 shall provide Counsel for the Designating Party with advance written notice, via electronic mail at least ten business days before disclosure. Such notice shall state the identity of the material for which disclosure is sought, the identity of the individual to whom disclosure would be made, and the reason for which disclosure is sought. Counsel for the Designating Party may challenge the proposed disclosure of material pursuant to this provision by providing counsel for the Party seeking disclosure with a written objection, via electronic mail, within the ten business-day period. If a written objection is made, the Party seeking to disclose shall not proceed with disclosure unless authorized to do so pursuant to the procedures described in Section 6 above (CHALLENGING CONFIDENTIALITY DESIGNATIONS).

8. PROTECTED MATERIAL SUBPOENAED OR ORDERED PRODUCED IN OTHER LITIGATION

If a Party is served with a subpoena or a court order issued in other litigation, investigation, or proceeding that compels disclosure of any information or items designated in this action as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY" that Party must:

- (a) promptly notify in writing the Designating Party. Such notification shall include a copy of the subpoena or court order;
- (b) promptly notify in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Protective Order. Such notification shall include a copy of this Order; and
- (c) cooperate with respect to all reasonable procedures sought to be pursued by the Designating Party whose Protected Material may be affected.

If the Designating Party timely seeks a protective order, the Party served with the subpoena or court order shall not produce any information designated in this action as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL—OUTSIDE ATTORNEYS' EYES ONLY" before a determination by the court from which the subpoena or order issued, unless the Party has obtained the Designating Party's permission. The Designating Party shall bear the burden and expense of seeking protection in that court of its confidential

material – and nothing in these provisions should be construed as authorizing or encouraging a Receiving Party in this action to disobey a lawful directive from another court.

9. <u>A NON-PARTY'S PROTECTED MATERIAL SOUGHT TO BE PRODUCED IN THIS LITIGATION</u>

- (a) The terms of this Order are applicable to information produced by a Non-Party in this action and designated as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY." Such information produced by Non-Parties in connection with this litigation is protected by the remedies and relief provided by this Order. Nothing in these provisions should be construed as prohibiting a Non-Party from seeking additional protections.
- (b) In the event that a Party is required, by a valid discovery request, to produce a Non-Party's confidential information in its possession, and the Party is subject to an agreement with the Non-Party not to produce the Non-Party's confidential information, then the Party shall:
- 1. promptly notify in writing the Requesting Party and the Non-Party that some or all of the information requested is subject to a confidentiality agreement with a Non-Party;
- 2. promptly provide the Non-Party with a copy of the Order in this litigation, the relevant discovery request(s), and a reasonably specific description of the information requested; and
- 3. make the information requested available for inspection by the Non-Party. This provision is without waiver of a Party's right to object to the discovery request or subpoena.
- (c) If the Non-Party fails to object or seek a protective order from this Court within 14 days of receiving the notice and accompanying information, the Party responding to a valid discovery request may produce the Non-Party's confidential information responsive to the discovery request, except that, if the Party from whom the discovery is sought has a contractual obligation to give a longer period of notice to the Non-Party, the Party shall so advise the Party requesting the discovery, and the Producing Party shall have no obligation to produce the Non-Party's material until the contractual notice period expires. If the Non-Party timely seeks a protective order, the Receiving Party shall not produce any information in its possession or control that is subject to the confidentiality agreement with the Non-Party before a determination by the Court. Absent a court order to the contrary, the Non-Party shall bear the burden and expense of seeking protection in this Court of its Protected Material.

10. <u>UNAUTHORIZED DISCLOSURE OF PROTECTED MATERIAL</u>

If a Receiving Party learns that, by inadvertence or otherwise, it has disclosed Protected Material to any person or in any circumstance not authorized under this Order, the Receiving Party must immediately (a) notify in writing the Designating Party of the unauthorized disclosures, (b) use its best efforts to retrieve all unauthorized copies of the Protected Material, (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Order, and (d) request such person or persons to execute the "Acknowledgment and Agreement to Be Bound" that is attached hereto as Exhibit A.

11. PRODUCTIONS AND USE OF PROTECTED HEALTH INFORMATION

- Insurance Portability and Accountability Act of 1996 (HIPAA), specifically, 45 C.F.R. § 164.512(e)(1)(ii)(B) and § 164.512(e)(1)(v), this Order is a HIPAA qualified Protective Order, as that term is defined in the foregoing regulations. In addition to the foregoing federal laws and regulations, this Order is entered to facilitate compliance with applicable state laws and regulations governing patient privacy and protecting healthcare information.
- All Covered Entities who receive or have already received in this action a discovery request are hereby authorized to disclose PHI to the extent necessary to comply with such a discovery request, provided, however, that nothing in this Order shall require any Covered Entity (or party) to produce PHI (*i.e.*, nothing in this Order shall affect other objections to such a discovery request, such as those unrelated to HIPAA). Covered Entities may disclose PHI pursuant to this Order to any Party in this action or to any Party's Counsel (including the agents and employees of the Parties and their Counsel) without violating the provisions of HIPAA. A Party producing documents of Covered Entities that contain PHI shall first stamp each document containing PHI with the following stamp: "Protected Health Information Subject to Stipulated Protective Order." Such stamp shall be in addition to the "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL OUTSIDE ATTORNEYS' EYES ONLY" legend affixed to such documents pursuant to Section 5.2(a), as appropriate.
- 11.3 All Parties and their Counsel (including the agents and employees of the Parties and their Counsel) are hereby authorized through discovery in this case to disclose, receive, subpoena, and transmit PHI. The Parties may not object to search terms designed to capture potentially relevant documents or information

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on the basis that the documents or information sought contain PHI protected by HIPAA.

- 11.4 Unless otherwise ordered by the Court or permitted in writing by the Designating Party, a Receiving Party may disclose PHI only as permitted pursuant to Section 7.2 for PHI designated "CONFIDENTIAL" or pursuant to Section 7.3 for PHI designated "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY."
- 11.5 Pursuant to 45 C.F.R. § 164.512(e)(1)(v)(A), the Parties and their Counsel shall be allowed to use or disclose PHI for this litigation, and any appeals, settlement, enforcement, or monitoring that may result. The Parties and their Counsel may not use the PHI for any other purpose. Authorized uses include disclosure to the Court and support staff, the Parties and the Parties' employees, their Counsel, the Counsel's firms (i.e., attorneys and support staff), the Parties' experts, consultants, mediators, court reporters, videographers, copy services, and e-discovery vendors.
- 11.6 If a Party wishes to file a document containing PHI with the Court, it must be filed under seal, following the appropriate procedures to do so in the applicable court. However, any Party may publicly file a pleading or document with the Court that describes, summarizes, or quotes PHI, as long as that Party redacts the name and date of birth of the Individual to whom the PHI pertains and complies with the de-identification requirements of 45 C.F.R. § 164.514, and simultaneously files an un-redacted version under seal, and provides a copy of the un-redacted version to the other Parties. Similarly, any Party may publicly file a document containing Deidentified Information relating to an Individual (such as a medical record), as long as that Party redacts the name and date of birth of the Individual to whom the information pertains and complies with the de-identification requirements of 45 C.F.R. § 164.514, and files an un-redacted version under seal, and provides a copy of the un-redacted version to the other Parties.
- 11.7 Any Party may discuss PHI covered by this Order at a deposition. The Party must request that this portion of the testimony be marked as "Protected Health Information Subject to Protective Order" in the deposition transcript. Any Party must comply with the redaction and de-identification requirements of this Order, as referenced in the preceding paragraph, before filing a deposition or portion of a deposition containing PHI with the Court.
- 11.8 Any Party may use documents containing PHI at trial, an evidentiary or other motion hearing, including but not limited to, introducing them into evidence and asking a witness about their contents. If a

Party moves a document containing PHI into evidence and wants it to be a part of the record, the Court shall appropriately instruct the Clerk on how to handle such documents.

12. <u>DESTRUCTION OF PROTECTED HEALTH INFORMATION AND INADVERTENT DISCLOSURE</u>

- 12.1 Pursuant to 45 C.F.R. § 164.512(e)(1)(v)(B), upon the final disposition of this action, as defined in Section 4 (DURATION), any recipient of PHI under this Order must comply with the provisions of Section 15 below (FINAL DISPOSITION).
- 12.2 If any Party learns that, by inadvertence or otherwise, PHI has been disclosed to or accessed by any person or in any circumstance not authorized under this Order, the Party must, not later than 10 calendar days after learning of the disclosure: (a) notify in writing relevant Parties, including the Covered Entity who supplied the PHI of the unauthorized disclosure or access; (b) if the Party is the one who made the unauthorized disclosure or access, use its best efforts to retrieve all PHI that was improperly disclosed or terminate the unauthorized access; (c) inform the person or persons to whom unauthorized disclosures or access were made of all the terms of this Order; and (d) request that such person or persons execute the "Acknowledgment and Agreement to Be Bound" (Exhibit A).

13. <u>INADVERTENT PRODUCTION OF PRIVILEGED OR OTHERWISE PROTECTED MATERIAL</u>

- 13.1 <u>Clawback Agreement.</u> The Parties agree that the production or disclosure of any documents and accompanying metadata protected from discovery under the attorney-client privilege, work product doctrine, opinion work product doctrine, the joint defense or common interest privilege, privacy laws and regulations or any other immunity or protection ("Protected Documents") does not result in waiver of any privilege or protection, including subject matter waiver, associated with such Protected Documents as to the Receiving Party or any third or non-parties in this or in any other state or federal proceeding solely by virtue of such production or disclosure. This Section provides the maximum protection allowed by Federal Rule of Evidence 502(d) with regard to Protected Documents. Federal Rule of Evidence 502(b) does not apply to any disputes regarding Protected Documents, and instead this Order governs all disputes regarding Protected Documents produced in this litigation. Nothing contained herein requires the production of Protected Documents.
 - 13.2 Discovery by Producing Party. In the event that a producing party discovers that it produced

- Protected Document(s), it shall provide written notice of the claim of privilege or protection to the receiving party (a "Clawback Notice"), sufficiently identifying the Protected Document(s) within a reasonable time. The Clawback Notice must be as specific as possible in identifying the basis for the privilege claimed, and must include at least the information required by Rule 26(b)(5)(A)(ii). That a particular basis or argument may not have been raised in the Clawback Notice does not, however, limit the Producing Party from raising that basis or argument in response to a challenge ultimately presented to the Court.
- (a) As soon as practicable or within a reasonable time after providing the Clawback Notice, the producing party shall provide (i) if only a portion of the document contains privileged or protected material, a new copy of the document utilizing the same bates number(s) as the original that has been redacted to protect the privilege or protected material; or (ii) if the entire document is privileged or protected, a slip sheet identifying the same bates number(s) as the original noting that the document has been withheld. Any Protected Document that is the subject of a Clawback Notice will be included on a privilege log if and as required by the privilege-logging procedures agreed to by the parties or ordered by the Court.
- (b) Within ten (10) business days of receipt of a Clawback Notice (regardless of whether the Receiving Party agrees with or plans to challenge the Producing Party's claim of privilege or protection), the Receiving Party must use reasonable efforts to return or destroy the Protected Document(s), and all copies thereof, and certify to the producing party when this return or destruction is complete. A Party receiving a Clawback Notice shall sequester or destroy any notes or other work product that refers to or excerpts the contents of the Protected Document.
- (c) If a Receiving Party challenges a claim that a Protected Document specified in a Clawback Notice is privileged or protected, the Receiving Party shall notify the Producing Party of its challenge within 14 business days of receiving the Clawback Notice. However, if one party issues Clawback Notices for more than 100 documents within a seven-day period, the Receiving Party may have an additional seven days business days to challenge the Clawback Notice. The Receiving Party's challenge notice must reasonably describe the anticipated grounds for the receiving party's challenge. That a particular basis or argument may not have been raised in the Receiving Party's original challenge notice does not, however, limit the Receiving Party from raising that basis or argument in the challenge ultimately presented to the Court.
 - (d) Within 14 business days of the Producing Party receiving notification of the challenge, the

parties shall meet and confer in an effort to resolve their disagreement. If the Parties are unable to resolve their disagreement, then the Parties will submit their dispute to the Court (or any assigned Magistrate Judge) in accordance with the applicable judge's standing order and/or rules. The Producing Party will submit all applicable Protected Document(s) for *in camera* review if any Party requests their submission or at the Court's (or Magistrate Judge's) request.

- (e) The Parties may agree to extend the time periods set forth in paragraphs (b), (c), and (d) as appropriate without an order from the Court if, after making reasonable efforts in good faith to meet the deadlines therein, the Parties agree that reasonable extensions are necessary.
- Discovery by Receiving Party. In the event that a Receiving Party discovers that it has received or examined Document(s) that it reasonably believes are or may be privileged or protected, the receiving party promptly shall: (i) stop reading or reviewing the document; (ii) sequester the Document(s); and (iii) within four business days of such discovery, notify the Producing Party of the possible production or disclosure by identifying the Bates range(s) of the Document the Receiving Party reasonably believes are or may be privileged or protected, and were or may have been produced or disclosed (a "Production Notice"). Upon the Producing Party receiving a Production Notice, if the Producing Party determines that the subject documents are privileged or protected, and timely serves a Clawback Notice within ten business days of receipt of the Production Notice, the Receiving Party shall use reasonable efforts to return or destroy the Protected Document(s) as described in Section 11.2 above, and the producing party shall promptly provide any replacement images as described in Section 11.2 above.
- Document is used or is about to be used in a deposition or court hearing or proceeding, the Producing Party must object on the record, state the basis for the privilege claim, and must demand that the document be clawed back.
- (a) If, in the case of a deposition, the Protected Document is capable of redaction to excise privileged material, the Party making the privilege claim must promptly make redactions to the document and permit the witness to testify as to the non-privileged material in the document. This redaction must be accomplished in such a way as to permit the deposition to continue with minimal disruption. Once alerted to the privilege claim, the Party conducting the deposition must avoid eliciting testimony about the portions of

the Protected Document that are claimed to be privileged, unless and until any disputes about the privilege claim are resolved. In all events, once the Protected Document is no longer in use at the deposition, the receiving party shall immediately return or destroy all copies of the Protected Document.

- (b) As to any deposition testimony subject to a claim of privilege or protection, the Party claiming privilege shall make the claim within ten business days of receiving a rough transcript, or if no rough transcript is received, within ten business days of receiving the final transcript, after which the Parties shall follow the procedures set forth above, as applicable. In the event the Court decides the clawback dispute in the Receiving Party's favor and the Receiving Party was denied the opportunity to examine a witness as to the materials at issue, the witness shall be made available as soon as practicable after the Court's decision to reasonably permit the examination that was previously prohibited.
- (c) If a Receiving Party uses discovery materials in a brief or at a hearing, and the Producing Party has not served a Clawback Notice as to those materials in advance of the briefing event or hearing, the Producing Party must promptly object and serve a Clawback Notice within ten business days of receipt of the briefing or the hearing. Thereafter, the procedures set forth above apply. To the extent any privileged or protected material is placed into the public record in connection with briefing or a hearing, and the Producing Party timely serves a Clawback Notice, the Receiving Party shall (a) withdraw the portion of the briefing and exhibits that contain privileged or protected material, (b) request the Court seal that material, or (c) join or not oppose a motion to seal the privileged or protected material pending the Court's resolution of any clawback dispute.
- (d) Notwithstanding the foregoing, any document used by any Party in a deposition or court filing in this action that a Producing Party does not clawback within ten business days of use shall not be eligible for clawback under this Order. Such ineligibility for clawback of that document under this Order shall not result in a subject matter waiver in any other state or federal proceeding.
- 13.5 <u>Prohibition On Use of Privileged Information</u>. To the extent any Party is aware that it has obtained Protected Documents, has received a Clawback Notice, or it is reasonably apparent that the Party has obtained privileged or protected information through production, disclosure, or communications, such Protected Documents and/or information may not be submitted to the Court, presented for admission into evidence, used to argue against privilege or protection, or sought in discovery in this proceeding or in any other

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15. FINAL DISPOSITION

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proceeding or action, unless and until the Court determines that Protected Document is not privileged or otherwise protected from discovery. The Party must promptly notify the Producing Party of its possession of such privileged information and certify the return or destruction of the Protected Documents and/or information within a reasonable time as described above.

14. **MISCELLANEOUS**

- Right to Further Relief. Nothing in this Order abridges the right of any person to seek its 14.1 modification by the Court in the future.
- 14.2 Right to Assert Other Objections. By stipulating to the entry of this Order, no Party waives any right it otherwise would have to object to disclosing or producing any information or item on any ground not addressed in this Order. Similarly, no Party waives any right to object on any ground to use in evidence of any of the material covered by this Order unless addressed in this Order.
- 14.3 Copy of Order. When discovery is sought from a Non-Party in this action after entry of this Order, a copy of this Order must accompany the discovery request.
- 14.4 Filing Protected Material. Without written permission from the Designating Party or a court order secured after appropriate notice to all interested persons, a Party may not file in the public record in this action any Protected Material. A Party that seeks to file under seal any Protected Material must comply with Civil Local Rule 79-5. Protected Material may only be filed under seal pursuant to a court order authorizing the sealing of the specific Protected Material at issue. Pursuant to Civil Local Rule 79-5, a sealing order will issue only upon a request establishing that the Protected Material at issue is privileged, protectable as a trade secret, or otherwise entitled to protection under the law. If a Receiving Party's request to file Protected Material under seal pursuant to Civil Local Rule 79-5 is denied by the Court, then the effect of the Court's ruling on the motion is as set forth in Civil Local Rule 79-5(g).

Within 60 days after the final disposition of this action, as defined in Section 4 (DURATION), each Receiving Party must return all Protected Material and PHI to the Producing Party or destroy such material. As used in this subdivision, "all Protected Material and PHI" includes all copies, abstracts, compilations, summaries, and any other format reproducing or capturing any of the Protected Material and PHI. Whether the Protected Material or PHI is returned or destroyed, the Receiving Party must submit a written certification to

the Producing Party (and, if not the same person or entity, to the Designating Party) by the 60-day deadline that: (1) identifies (by category, where appropriate) all the Protected Material and PHI that was returned or destroyed; and (2) affirms that the Receiving Party has not retained any copies, abstracts, compilations, summaries or any other format reproducing or capturing any of the Protected Material or PHI. Notwithstanding this provision, Counsel are entitled to retain an archival copy of all pleadings, motion papers, trial, deposition, and hearing transcripts, legal memoranda, correspondence, deposition and trial exhibits, expert reports, attorney work product, and consultant and expert work product, even if such materials contain Protected Material and PHI. Any such archival copies that contain or constitute Protected Material or PHI remain subject to this Order as set forth in Section 4 (DURATION).

AS MODIFIED BY THE COURT, ^IT IS SO ORDERED.

DATED: March 20, 2025

Honorable Virginia K. DeMarchi United States Magistrate Judge

1 EXHIBIT A 2 ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND 3 I, [print full of or type name], _____[print or type full address], declare under penalty 4 of perjury that I have read in its entirety and understand the Stipulated Protective Order that was issued by the 5 United States District Court for the Northern District of California in the case of Teva Pharmaceuticals USA, 6 Inc. v. Corcept Therapeutics, Inc., et. al., No. 5:24-cv-03567-NW (N.D. Cal.). I agree to comply with and to 7 8 be bound by all the terms of this Stipulated Protective Order and I understand and acknowledge that failure to 9 so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I 10 will not disclose in any manner any information or item that is subject to this Stipulated Protective Order to any person or entity except in strict compliance with the provisions of this Order. 11 12 I further agree to submit to the jurisdiction of the United States District Court for the Northern District 13 of California for the purpose of enforcing the terms of this Stipulated Protective Order, even if such 14 enforcement proceedings occur after termination of this action. 15 I hereby appoint [print type full name] of _____ [print or type full address and telephone number] as my 16 17 California agent for service of process in connection with this action or any proceedings related to enforcement 18 of this Stipulated Protective Order. 19 20 21 22 City and State where sworn and signed: 23 Printed name: _ 24 [printed name] 25 Signature: ____ 26 [signature] 27 28